Destiny Rezendes @dezzie_rezzie

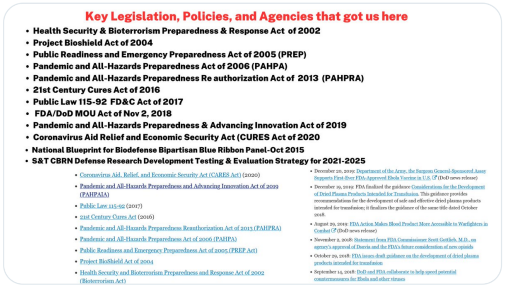
Apr 25 • 21 tweets • dezzie_rezzie/status/1650878903211130880

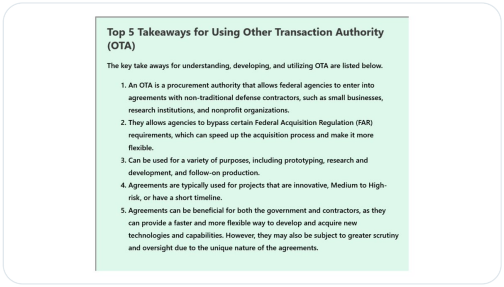
1🧵"The Road to Hell is paved w/ good intentions"= "The road to the NWO is paved w/ government policies." Since Project BioShield (2004) there has been 25+ laws/acts, policies that, like cobblestones, have been created to lay out the road we now find ourselves on.

OPERATION WARP SPEED
Catastrophic Contagion
A NATIONAL BLUEPRINT FOR BIODEFENSE:
LEADERSHIP AND MAJOR REFORM NEEDED TO OPTIMIZE EFFORTS
BIPARTISAN REPORT OF THE BLUE RIBBON STUDY PANEL ON BIODEFENSE
National Health Security Strategy 2019-2022
EVENT 201
ASPR
Mission Possible: Quenching Epidemics
U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses
Ebola and Other Emerging Health Threats
S&T Chemical, Biological, Radiological, Nuclear Defense Research, Development, Testing & Evaluation Strategy 2021-2025
September 2021
USAID | PREDICT
REDUCING PANDEMIC RISK, PROMOTING GLOBAL HEALTH

2🧵In the name of security, steps were taken, words created & laws were signed. The pandemic & what lies ahead relies on a handful of seemingly harmless acronyms: MOU, GoF, CRADA, OTA, DURCS, MPP, MCMs-etc. I aim to untangle C-19 & the messy double-speak for us all.

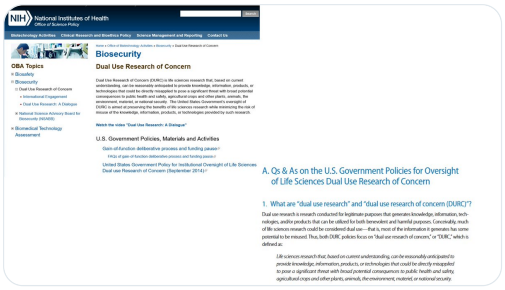
Key Legislation, Policies, and Agencies that got us here
• US GoF Deliberative Process and Research Funding Pause -Nov 2014
Planning Guidance for Recovery Following Biological Incidents DHS-May 2009
CRITICAL ANALYSIS OF BIOTERRORIST INCIDENTS,NATIONAL EXERCISES AND U.S. PREVENTION:USAF- April 2011
National Science Advisory Board for Biosecurity- 27 Nov 2012
World Bank: Financing Pandemics -Dec 2017
CEPI: Financing Pandemics-May 2017
The Apollo Program Bipartisan Commission on Biodefense- Jan 2021
A Global Deal for Our Pandemic Age: G20- Jan 2021
Outbreak Readiness & Business Impact Protecting Lives & Livelihoods across the Global Economy- Jan 2021
Financing the Global Commons for Pandemic Preparedness and Response: G20- Jan 2021
• Memorandum of Understanding (MOU) 225-19-001
The Athena Agenda: Bipartisan Commission on Biodefense- April 2022

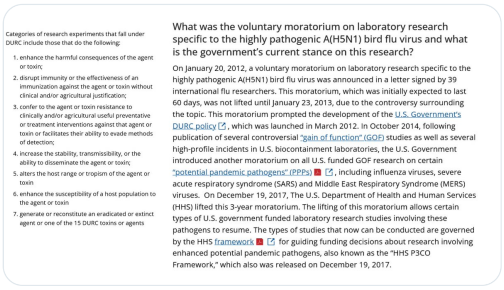

Key Legislation, Policies, and Agencies that got us here
• Health Security & Bioterrorism Preparedness & Response Act of 2002
• Project Bioshield Act of 2004
• Public Readiness and Emergency Preparedness Act of 2005 (PREP)
• Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA)
• Pandemic and All-Hazards Preparedness Re authorization Act of 2013 (PAHPRA)
• 21st Century Cures Act of 2016
• Public Law 115-92 FD&C Act of 2017
• FDA/DoD MOU Act of Nov 2, 2018
• Pandemic and All-Hazards Preparedness & Advancing Innovation Act of 2019
• Coronavirus Aid Relief and Economic Security Act (CURES Act of 2020
• National Blueprint for Biodefense Bipartisan Blue Ribbon Panel-Oct 2015
• S&T CBRN Defense Research Development Testing & Evaluation Strategy for 2021-2025


Top 5 Takeaways for Using Other Transaction Authority (OTA)
The key take aways for understanding, developing, and utilizing OTA are listed below.
1. An OTA is a procurement authority that allows federal agencies to enter into agreements with non-traditional defense contractors, such as small businesses, research institutions, and nonprofit organizations.
2. They allows agencies to bypass certain Federal Acquisition Regulation (FAR) requirements, which can speed up the acquisition process and make it more flexible.
3. Can be used for a variety of purposes, including prototyping, research and development, and follow-on production.
4. Agreements are typically used for projects that are innovative, Medium to High-risk, or have a short timeline.
5. Agreements can be beneficial for both the government and contractors, as they can provide a faster and more flexible way to develop and acquire new technologies and capabilities. However, they may also be subject to greater scrutiny and oversight due to the unique nature of the agreements.

3🧵Prior to the 2014 moratorium on GoF (due to several high-profile incidents at US biolabs) there was in Jan 2012 a moratorium placed on on DURCs & it was lifted a yr later. Thankfully for the oversight in that case kept things in check.

Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies
Prepared by the National Institutes of Health on behalf of the United States Government
September 2014


National Institutes of Health
Office of Science Policy
OBA Topics
Biosecurity
Dual Use Research of Concern
Biosecurity
Dual Use Research of Concern
U.S. Government Policies, Materials and Activities
A. Qs & As on the U.S. Government Policies for Oversight of Life Sciences Dual Use Research of Concern
1. What are "dual use research" and "dual use research of concern (DURC)"?



Categories of research experiments that fall under DURC include those that do the following:

1. enhance the harmful consequences of the agent or toxin;
2. disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. confer to the agent or toxin resistance to clinically and/or agricultural useful preventative or treatment interventions against that agent or toxin or facilitates their ability to evade methods of detection;
4. increase the stability, transmissibility, or the ability to disseminate the agent or toxin;
5. alters the host range or tropism of the agent or toxin
6. enhance the susceptibility of a host population to the agent or toxin
7. generate or reconstitute an eradicated or extinct agent or one of the 15 DURC toxins or agents

What was the voluntary moratorium on laboratory research specific to the highly pathogenic A(H5N1) bird flu virus and what is the government's current stance on this research?

On January 20, 2012, a voluntary moratorium on laboratory research specific to the highly pathogenic A(H5N1) bird flu virus was announced in a letter signed by 39 international flu researchers. This moratorium, which was initially expected to last 60 days, was not lifted until January 23, 2013, due to the controversy surrounding the topic. This moratorium prompted the development of the U.S. Government's DURC policy, which was launched in March 2012. In October 2014, following publication of several controversial "gain of function" (GOF) studies as well as several high-profile incidents in U.S. biocontainment laboratories, the U.S. Government introduced another moratorium on all U.S. funded GOF research on certain "potential pandemic pathogens" (PPPs), including influenza viruses, severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome (MERS) viruses. On December 19, 2017, The U.S. Department of Health and Human Services (HHS) lifted this 3-year moratorium. The lifting of this moratorium allows certain types of U.S. government funded laboratory research studies involving these pathogens to resume. The types of studies that now can be conducted are governed by the HHS framework for guiding funding decisions about research involving enhanced potential pandemic pathogens, also known as the "HHS P3CO Framework," which also was released on December 19, 2017.

4🧵A DURC= Dual Use Research of Concern. DURC research involves work on pathogens that have already been identified as having the potential for bioterrorism OR can yield beneficial research. Unlike GoF, the goal is NOT to alter or enhance a pathogen.

6. Why is the scope of the *Policy for Institutional Oversight of Life Sciences DURC* limited to research with the 15 listed agents and toxins?

Because oversight of DURC will be a new undertaking for many institutions, the USG has limited the scope of the *Policy for Institutional Oversight of Life Sciences DURC* (Section 6.2), as well as that of the *March 2012 DURC Policy* (Section III), to a subset of life sciences research that involves 15 agents and toxins and seven categories of experiments. The USG will solicit feedback on the experience of institutions in implementing the *Policy for Institutional Oversight of Life Sciences DURC*. The USG will assess the benefits and risks of expanding the scope of the *Policy for Institutional Oversight of Life Sciences DURC*, and will update the Policy as warranted.

7. Does the USG Policy for Institutional Oversight of Life Sciences DURC apply only to federally funded research, or does it apply more broadly?

If an institution (1) receives any federal funding for any life sciences research, and (2) is conducting work with one or more of the 15 agents and toxins listed in the policy, then any research at that institution with those 15 agents and toxins - regardless of the source of funding - must comply with the requirements articulated in the policy.

Categories of research experiments that fall under DURC include those that do the following:

1. enhance the harmful consequences of the agent or toxin;
2. disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. confer to the agent or toxin resistance to clinically and/or agricultural useful preventative or treatment interventions against that agent or toxin or facilitates their ability to evade methods of detection;
4. increase the stability, transmissibility, or the ability to disseminate the agent or toxin;
5. alters the host range or tropism of the agent or toxin
6. enhance the susceptibility of a host population to the agent or toxin
7. generate or reconstitute an eradicated or extinct agent or one of the 15 DURC toxins or agents

A. Qs & As on the U.S. Government Policies for Oversight of Life Sciences Dual Use Research of Concern

1. What are "dual use research" and "dual use research of concern (DURC)"?

Dual use research is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for both benevolent and harmful purposes. Conceivably, much of life sciences research could be considered dual use—that is, most of the information it generates has some potential to be misused. Thus, both DURC policies focus on "dual use research of concern," or "DURC," which is defined as:

> *Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.*

NIH National Institutes of Health
Office of Science Policy
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Biotechnology Activities
Clinical Research and Bioethics Policy
Science Management and Reporting
Contact Us
Home » Office of Biotechnology Activities » Biosecurity » Dual Use Research of Concern
OBA Topics
Biosafety
Biosecurity
Dual Use Research of Concern
International Engagement
Dual Use Research: A Dialogue
National Science Advisory Board for Biosecurity (NSABB)
Biomedical Technology Assessment
Biosecurity
Dual Use Research of Concern
Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The United States Government's oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.
Watch the video "Dual Use Research: A Dialogue"
U.S. Government Policies, Materials and Activities
Gain-of-function deliberative process and funding pause
FAQs of gain-of-function deliberative process and funding pause
United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern (September 2014)

5🧵Congress has yet to ask EcoHealth or Fauci what type of research was being done at WIV? Was it DURC or GoF? There are differences. Being that Daszak, here, is listed as the Principal Investigator, DURC appears to be more likely.

Principal Investigator/Program Director (Last, first, middle): Daszak, Peter

Daszak, Peter

and their students at 6 leading institutes of public health, veterinary medicine, and environmental science in the USA.

East China Normal University. Shanghai, China (Shuyi Zhang and Guangjian Zhu)
Dr. Zhang is Dean of the Institutes for Advanced Interdisciplinary Research at East China Normal University. Over [redacted] square metres is allocated to his research group at ECNU. The lab is fully capable of carrying out molecular, protein, epidemic disease and evolution research. Experimental equipment includes: Roche 454 (GS FLX Titanium System), Bioinformatics Compuser Server, Multi-Channel Neurophysiology Workstation TDT, PCR Amplifier, Real time PCR Amplifier, Electrophoresis, Ultra-low Temperature Freezer, Centrifuge, UV-Visible Spectrophotometer, Two-dimensional Electrophoresis, Vertical Electrophoresis System, Incubator, Clean Bench, and Class II-Biosafety Cabinet, Hybridization Oven, Water PurificationSystem, and Shaker.

Wuhan Institute of Virology, Wuhan, China (Zhengli Shi and Xingyi Ge)
The Shi laboratory includes 4 rooms totaling [redacted], one equipped with two CO2 incubators for tissue culture, one equipped facilities including with high speed centrifuge, 2 -20°C, 3 -80°C freezers, 2 PCR machines, 1 ELISA plate reader, one for molecule diagnosis equipped with two biosafety cabinets, and one normal laboratory equipped

DURCS refers to research that has the potential to be used for beneficial or nefarious purposes.
DURCS only apply to Federally Funded research
DURCS can be research that creates a virus but not intentionally enhance it's functions
DURCS however can result in accidentally creating a potential bio-weapon by accidentally creating a more contagious and more lethal strain of a virus.

This differs from GoF because:

GoF is research that intentionally attempts to enhance a virus to gain more functionality either in transmissibility or in severity of infection /lethality.
GoF tries to alter a pathogen w/ the aim of understanding disease mechanisms to possibly discover & develop new treatments and not just for the sake of research.

BOTH DURCS & GoFs have had moratoriums placed on them because of their inherent risks:

DURCS's moratorium was lifted after a year from being issued.

GoF's moratorium was not lifted

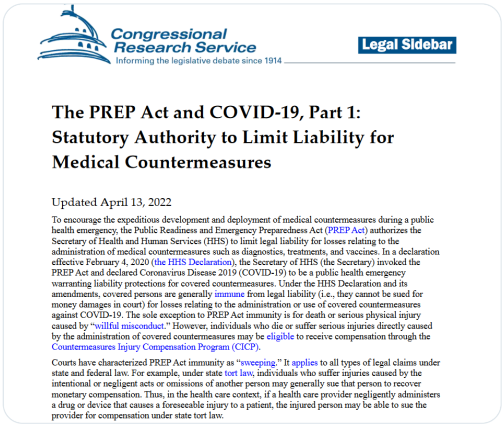
BOTH DURCS & GoFs have the potential to be helpful or harmful.

BOTH DURCS & GoFs : require oversight and are lab centered research methods and both can result creating a pandemic or aide in creating medical countermeasures.

Implementation of the *USG Policy for Institutional Oversight of Life Sciences DURC*: Illustrative Case Studies

The purpose of the *USG Policy for Institutional Oversight of Life Sciences DURC* is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, and technologies provided by such research. The Policy requires research institutions to establish a process for identifying dual use research of concern (DURC) and to implement risk mitigation measures for conducting and communicating such research. In the first step in this process, the principal investigator (PI) identifies research involving one or more of the 15 agents or toxins listed in the policy, and assesses whether the research can be reasonably anticipated to produce any of the seven listed experimental effects. The PI then refers the relevant research, including his/her assessment, to an Institutional Review Entity (IRE). The IRE reviews the PI's assessment and determines whether indeed the research involves any of the seven experimental effects, and if so, the IRE determines whether the research meets the definition of DURC, as defined in the policy. The IRE then works with the PI and the USG funding agency to develop a risk mitigation plan for responsibly conducting and communicating the DURC.

6🧵The situation we are in is a result of methods of research (Gof or DURC) + resulting MCMs. Both require and have policies. Not only did the research point towards intentionality, but so does the policies, set up JUST in time for C19.


Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures

Updated April 13, 2022

To encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective February 4, 2020 (the HHS Declaration), the Secretary of HHS (the Secretary) invoked the PREP Act and declared Coronavirus Disease 2019 (COVID-19) to be a public health emergency warranting liability protections for covered countermeasures. Under the HHS Declaration and its amendments, covered persons are generally immune from legal liability (i.e., they cannot be sued for money damages in court) for losses relating to the administration or use of covered countermeasures against COVID-19. The sole exception to PREP Act immunity is for death or serious physical injury caused by "willful misconduct." However, individuals who die or suffer serious injuries directly caused by the administration of covered countermeasures may be eligible to receive compensation through the Countermeasures Injury Compensation Program (CICP).

Courts have characterized PREP Act immunity as "sweeping." It applies to all types of legal claims under state and federal law. For example, under state tort law, individuals who suffer injuries caused by the intentional or negligent acts or omissions of another person may generally sue that person to recover monetary compensation. Thus, in the health care context, if a health care provider negligently administers a drug or device that causes a foreseeable injury to a patient, the injured person may be able to sue the provider for compensation under state tort law.

Dec 02, 2018

The MOU formally establishes the framework under which the DoD and the FDA will implement the law passed by Congress in 2017 for enhanced engagements between the DoD and the FDA. Under the terms of this MOU, the FDA will work closely with the DoD to evaluate how best to foster access to safe and effective medical products that serve the military's medical needs; give the highest level of attention to and expedite review of priority DoD medical products; provide ongoing technical advice to aid in the rapid development and manufacturing of medical products for use by the military; and examine products currently under development to determine opportunities to streamline, review and expedite their availability. The 2017 law also expanded the FDA's authority to authorize emergency uses of medical products to reduce deaths and severity of injuries caused by chemical, biological, radiological or nuclear (CBRN) agents or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the U.S. military forces and for other purposes.

As part of the ongoing and frequent collaborations between the FDA and the DoD, additional steps taken over the past several months include:

- In July 2018, the FDA granted an Emergency Use Authorization (EUA) for the DoD's emergency use of Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma manufactured by the Centre de Transfusion Sanguine des Armées (often referred to as French freeze-dried Plasma). That action reflected the importance that both the DoD and the FDA place on efficiently prioritizing and expediting availability of potentially life-saving biological products that are essential to the urgent care of military personnel, especially those in potential battlefield settings. Granting this authorization supported access to this important product and ensures that it will be available if needed.
- In July 2018, the FDA approved the atropine autoinjector device as a medical countermeasure for chemical nerve agent exposure. This drug-device product was developed in partnership with the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, and was approved six months ahead of the DoD's product development schedule.

Jan 3, 2019

"Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAPHIA)

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019. It aims to improve the preparedness and response of the United States to public health emergencies. The document proposes several amendments to existing laws to achieve this goal. Some of the key amendments include:

- Improving coordination among federal, state, local, tribal, and territorial entities to prevent, detect, and respond to outbreaks of plant or animal disease that could compromise national security.
- Assessing current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities.
- Evaluating evidence-based benchmarks and objective standards required under the law to track progress towards preparedness goals.
- Authorizing appropriations for public health security grants and the Partnership for State and Regional Hospital Preparedness.

Overall, the it aims to enhance the ability of the United States to respond to public health emergencies and protect the health and safety of its citizens.

One Hundred Sixteenth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and nineteen

An Act

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Reference to Act.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

Sec. 201. Improving benchmarks and standards for preparedness and response.
Sec. 202. Public health emergency medical countermeasures enterprise.
Sec. 203. Regional health care emergency preparedness and response systems.
Sec. 204. Hospital preparedness program.
Sec. 205. Public health and health care system situational awareness and information sharing.
Sec. 206. Strengthening and supporting the public health emergency rapid response fund.

FDA

MOU 225-13-0028

MEMORANDUM OF UNDERSTANDING CONCERNING
INFORMATION-SHARING EXCHANGES INVOLVING FDA
AMONG AGENCIES PARTICIPATING IN THE
PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE (PHEMCE)
OFFICES AND AGENCIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES:
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTES OF HEALTH
FOOD AND DRUG ADMINISTRATION AND
THE DEPARTMENT OF DEFENSE
THE DEPARTMENT OF HOMELAND SECURITY
THE DEPARTMENT OF VETERANS AFFAIRS
THE DEPARTMENT OF AGRICULTURE

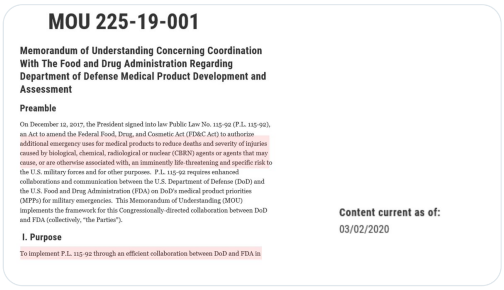
Content current as of:
04/09/2019

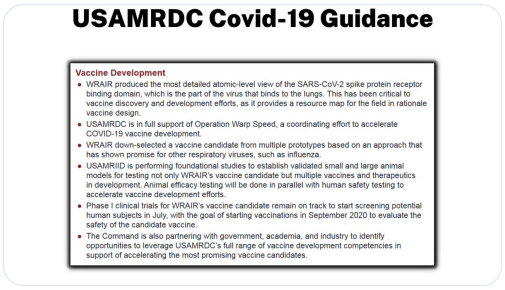
Preamble:

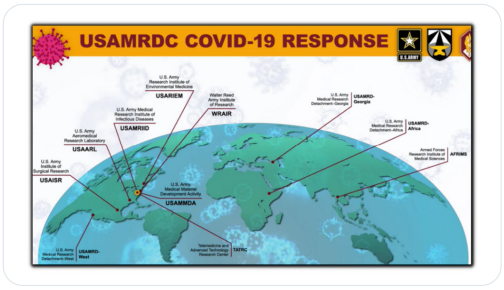
The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is a coordinated interagency effort which is responsible for, *inter alia*, focusing research, development, and procurement activities to provide medical countermeasures that will be safe and effective for use in the event of a public health or medical emergency. The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) of the Department of Health and Human Services (HHS) and includes three primary HHS internal agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Biomedical Advanced Research and Development Authority (BARDA) is also established within ASPR. The PHEMCE also includes other key federal partners: the Department of Homeland Security (DHS), the Department of Defense (DoD), including certain core components specified herein, the Department of Veterans Affairs (VA), and the Department of Agriculture. These offices, agencies, and Departments are thus considered and hereafter referred to in this document as PHEMCE Partners or Partners.

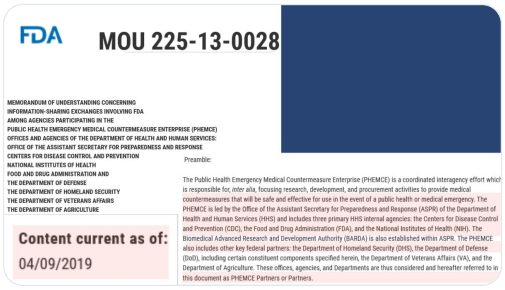
7🧵The Pandemic All Hazard Preparedness & Advancing Innovation Act of 2019, P.L 115-92 of Dec 2017 & the FDA/DoD collaboration MOU of Nov 2018, PHEMCE MOU 225-13-0028 of April 2019, World Banks report on "Financing Pandemics" in Dec 2017. All KEY to C19.

8🧵The MOU (PL 115-92) united USAMRDC, JPEO-CBRND, & the FDA in Dec 2017 to amend the FD&C Act. which authorized the FDA to expedite MCMs that are “reasonably likely to diagnose, prevent, treat or mitigate” health risks that could affect the military.


MOU 225-19-001
Memorandum of Understanding Concerning Coordination With The Food and Drug Administration Regarding Department of Defense Medical Product Development and Assessment
Preamble
On December 12, 2017, the President signed into law Public Law No. 115-92 (P.L. 115-92), an Act to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by biological, chemical, radiological or nuclear (CBRN) agents or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the U.S. military forces and for other purposes. P.L. 115-92 requires enhanced collaborations and communication between the U.S. Department of Defense (DoD) and the U.S. Food and Drug Administration (FDA) on DoD's medical product priorities (MPPs) for military emergencies. This Memorandum of Understanding (MOU) implements the framework for this Congressionally-directed collaboration between DoD and FDA (collectively, "the Parties").
I. Purpose
To implement P.L. 115-92 through an efficient collaboration between DoD and FDA in
Content current as of:
03/02/2020

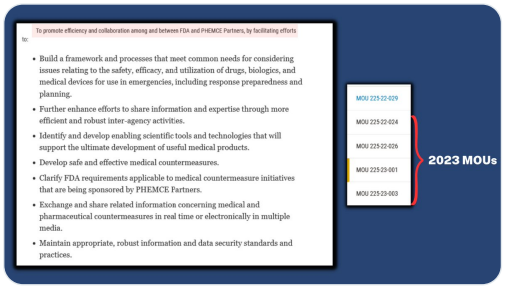

USAMRDC Covid-19 Guidance
Vaccine Development
WRAIR produced the most detailed atomic-level view of the SARS-CoV-2 spike protein receptor binding domain, which is the part of the virus that binds to the lungs. This has been critical to vaccine discovery and development efforts, as it provides a resource map for the field in rationale vaccine design.
USAMRDC is in full support of Operation Warp Speed, a coordinating effort to accelerate COVID-19 vaccine development.
WRAIR down-selected a vaccine candidate from multiple prototypes based on an approach that has shown promise for other respiratory viruses, such as influenza.
USAMRIID is performing foundational studies to establish validated small and large animal models for testing not only WRAIR's vaccine candidate but multiple vaccines and therapeutics in development. Animal efficacy testing will be done in parallel with human safety testing to accelerate vaccine development efforts.
Phase I clinical trials for WRAIR's vaccine candidate remain on track to start screening potential human subjects in July, with the goal of starting vaccinations in September 2020 to evaluate the safety of the candidate vaccine.
The Command is also partnering with government, academia, and industry to identify opportunities to leverage USAMRDC's full range of vaccine development competencies in support of accelerating the most promising vaccine candidates.

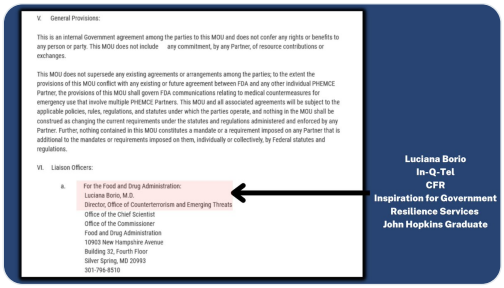



FDA
MOU 225-13-0028
MEMORANDUM OF UNDERSTANDING CONCERNING INFORMATION-SHARING EXCHANGES INVOLVING FDA AMONG AGENCIES PARTICIPATING IN THE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE (PHEMCE) OFFICES AND AGENCIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES: OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL INSTITUTES OF HEALTH FOOD AND DRUG ADMINISTRATION AND THE DEPARTMENT OF DEFENSE THE DEPARTMENT OF HOMELAND SECURITY THE DEPARTMENT OF VETERANS AFFAIRS THE DEPARTMENT OF AGRICULTURE
Content current as of:
04/09/2019
Preamble:
The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is a coordinated interagency effort which is responsible for, inter alia, focusing research, development, and procurement activities to provide medical countermeasures that will be safe and effective for use in the event of a public health or medical emergency. The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) of the Department of Health and Human Services (HHS) and includes three primary HHS internal agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Biomedical Advanced Research and Development Authority (BARDA) is also established within ASPR. The PHEMCE also includes other key federal partners: the Department of Homeland Security (DHS), the Department of Defense (DoD), including certain constituent components specified herein, the Department of Veterans Affairs (VA), and the Department of Agriculture. These offices, agencies, and Departments are thus considered and hereafter referred to in this document as PHEMCE Partners or Partners.

9🧵Out of the 6 MOU’s in this area, only 225-13-0028 predated C19. The more recent MOUs have been in 2022-23 & the Liaison officer in charge of this on behalf of the FDA is Luciana Borio. VP of the CIA’s In-Q-Tel, Former director at the NSC.

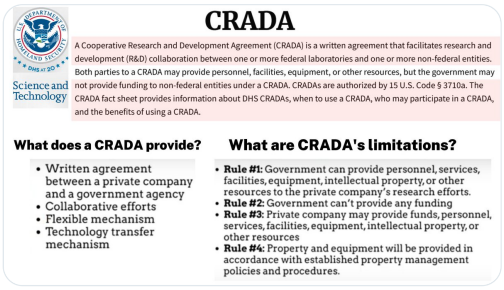
Dec 02, 2018
FDA and DoD formalize collaboration to advance medical products in support of American military personnel
New Memorandum of Understanding aligns agency efforts to foster the development and use of safe and effective medical products for members of the U.S. military
For Immediate Release: December 02, 2018
Today, the U.S. Food and Drug Administration and the Department of Defense's (DoD) Office of Health Affairs signed a Memorandum of Understanding regarding medical product development and assessment. This builds upon the work of both agencies to foster and prioritize the efficient development of safe and effective medical products intended to save the lives of American service members.
"We're extremely grateful to the men and women who defend our nation, often at great personal risk and sacrifice. It's our honor and duty to support our military personnel by ensuring they have access to safe and effective medical products -- especially products that meet the unique needs and settings in which soldiers may require medical treatment," said FDA Commissioner Scott Gottlieb, M.D. "The FDA has already been working closely with the DoD to identify opportunities to expedite availability of medical products, particularly those products used to treat injuries in battlefield settings. For example, as noted below, the Emergency Use Authorization for French freeze-dried plasma that was issued earlier this year. Our close collaboration with DoD has helped us target and more efficiently address DoD's immediate product priorities and foster development and review of these products in the most streamlined manner possible. We are looking forward to additional partnership opportunities under the MOU."


To promote efficiency and collaboration among and between FDA and PHEMCE Partners, by facilitating efforts
to:
Build a framework and processes that meet common needs for considering issues relating to the safety, efficacy, and utilization of drugs, biologics, and medical devices for use in emergencies, including response preparedness and planning.
Further enhance efforts to share information and expertise through more efficient and robust inter-agency activities.
Identify and develop enabling scientific tools and technologies that will support the ultimate development of useful medical products.
Develop safe and effective medical countermeasures.
Clarify FDA requirements applicable to medical countermeasure initiatives that are being sponsored by PHEMCE Partners.
Exchange and share related information concerning medical and pharmaceutical countermeasures in real time or electronically in multiple media.
Maintain appropriate, robust information and data security standards and practices.
MOU 225-22-029
MOU 225-22-024
MOU 225-22-026
MOU 225-23-001
MOU 225-23-003
2023 MOUs

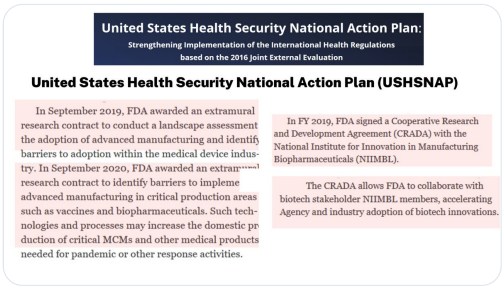

V. General Provisions:
This is an internal Government agreement among the parties to this MOU and does not confer any rights or benefits to any person or party. This MOU does not include any commitment, by any Partner, of resource contributions or exchanges.
This MOU does not supersede any existing agreements or arrangements among the parties; to the extent the provisions of this MOU conflict with any existing or future agreement between FDA and any other individual PHEMCE Partner, the provisions of this MOU shall govern FDA communications relating to medical countermeasures for emergency use that involve multiple PHEMCE Partners. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the parties operate, and nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by any Partner. Further, nothing contained in this MOU constitutes a mandate or a requirement imposed on any Partner that is additional to the mandates or requirements imposed on them, individually or collectively, by Federal statutes and regulations.
VI. Liaison Officers:
a. For the Food and Drug Administration:
Luciana Borio, M.D.
Director, Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Fourth Floor
Silver Spring, MD 20993
301-796-8510
Luciana Borio
In-Q-Tel
CFR
Inspiration for Government
Resilience Services
John Hopkins Graduate

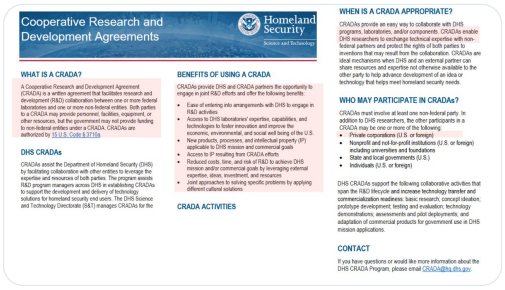
10🧵This new Military/Academia/Pharma/Intelligence collaboration & control mechanism should be alarming to everyone. It not only controls the research but the medical countermeasures (MCMs)+ has the leverage to force/coerce us into bio-tyranny.

11🧵On the MCM side of C19, the earlier mentioned legislation also applied to methods of production/response of which two types were used in the MCMs. The first was Cooperative Research & Development Agreements (CRADA.)

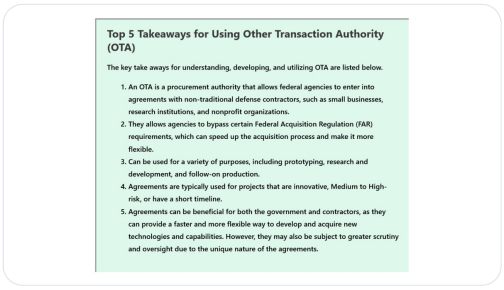

CRADA
Science and Technology
A Cooperative Research and Development Agreement (CRADA) is a written agreement that facilitates research and development (R&D) collaboration between one or more federal laboratories and one or more non-federal entities. Both parties to a CRADA may provide personnel, facilities, equipment, or other resources, but the government may not provide funding to non-federal entities under a CRADA. CRADAs are authorized by 15 U.S. Code § 3710a. The CRADA fact sheet provides information about DHS CRADAs, when to use a CRADA, who may participate in a CRADA, and the benefits of using a CRADA.
What does a CRADA provide?
• Written agreement between a private company and a government agency
• Collaborative efforts
• Flexible mechanism
• Technology transfer mechanism
What are CRADA's limitations?
• Rule #1: Government can provide personnel, services, facilities, equipment, intellectual property, or other resources to the private company's research efforts.
• Rule #2: Government can't provide any funding
• Rule #3: Private company may provide funds, personnel, services, facilities, equipment, intellectual property, or other resources
• Rule #4: Property and equipment will be provided in accordance with established property management policies and procedures.

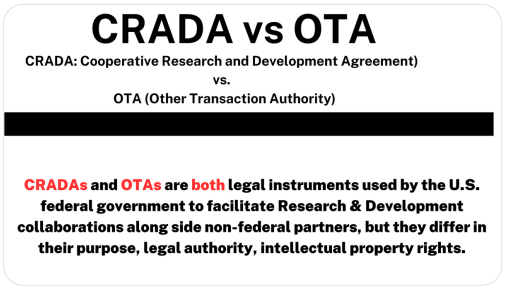
What is the benefit of CRADA?
• Provide incentives
• Protect any proprietary information
• Allow all parties to the CRADA to keep research results
• Share patents and patent licenses
• Permit one partner to retain exclusive rights to a patent or patent license
Who qualifies for a CRADA?
• Private corporations
• Nonprofit and not-for-profit institutions
• U.S. State and local governments
• Other U.S. federal agencies


United States Health Security National Action Plan:
Strengthening Implementation of the International Health Regulations based on the 2016 joint External Evaluation
United States Health Security National Action Plan (USHSNAP)
In September 2019, FDA awarded an extramural research contract to conduct a landscape assessment the adoption of advanced manufacturing and identify barriers to adoption within the medical device industry. In September 2020, FDA awarded an extramural research contract to identify barriers to impleme advanced manufacturing in critical production areas such as vaccines and biopharmaceuticals. Such technologies and processes may increase the domestic pr duction of critical MCMs and other medical products needed for pandemic or other response activities.
In FY 2019, FDA signed a Cooperative Research and Development Agreement (CRADA) with the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).
The CRADA allows FDA to collaborate with biotech stakeholder NIIMBL members, accelerating Agency and industry adoption of biotech innovations.

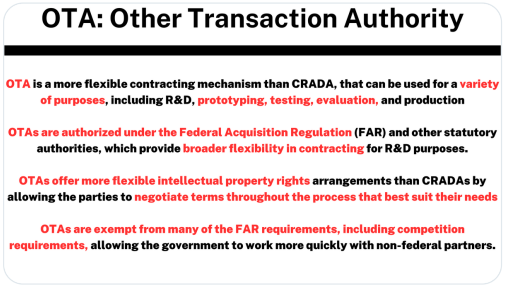


12🧵The other response method for MCMs was OTA's (other transaction agreements). They are similar but the differences are critical to their function.

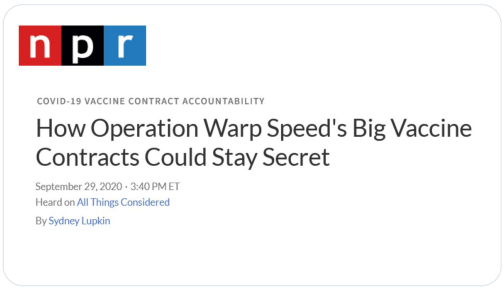

Top 5 Takeaways for Using Other Transaction Authority (OTA)
The key take aways for understanding, developing, and utilizing OTA are listed below.
1. An OTA is a procurement authority that allows federal agencies to enter into agreements with non-traditional defense contractors, such as small businesses, research institutions, and nonprofit organizations.
2. They allows agencies to bypass certain Federal Acquisition Regulation (FAR) requirements, which can speed up the acquisition process and make it more flexible.
3. Can be used for a variety of purposes, including prototyping, research and development, and follow-on production.
4. Agreements are typically used for projects that are innovative, Medium to High-risk, or have a short timeline.
5. Agreements can be beneficial for both the government and contractors, as they can provide a faster and more flexible way to develop and acquire new technologies and capabilities. However, they may also be subject to greater scrutiny and oversight due to the unique nature of the agreements.

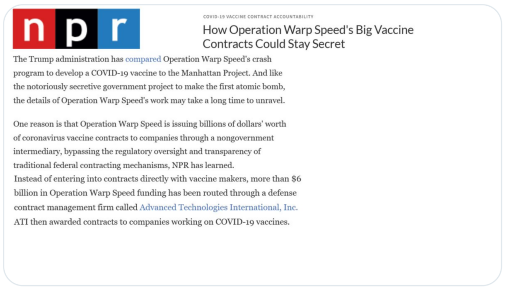

CRADA vs OTA
CRADA: Cooperative Research and Development Agreement)
vs.
OTA (Other Transaction Authority)
CRADAs and OTAs are both legal instruments used by the U.S. federal government to facilitate Research & Development collaborations along side non-federal partners, but they differ in their purpose, legal authority, intellectual property rights.

CRADA: Cooperative Research and Development Agreement) and an OTA (Other Transaction Authority)
CRADAs : typically used for R&D collaborations between a federal laboratory & a non-federal partner to develop and commercialize new technologies or products
Under a CRADA, the parties negotiate the terms of intellectual property rights ownership and licensing in advance of the research collaboration.
CRADAs are authorized by the Federal Technology Transfer Act, which provides statutory authority for federal laboratories to enter into cooperative research agreements with non-federal partners.
CRADAs are subject to competition requirements under the Federal Acquisition Regulation (FAR) and must be awarded to the non-federal partner through a competitive process.

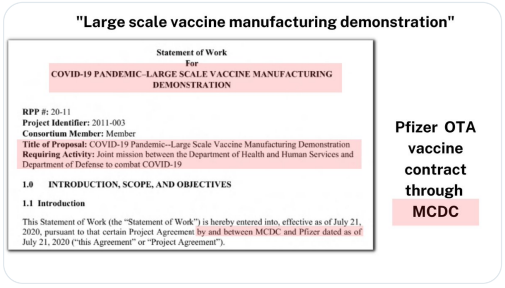

OTA: Other Transaction Authority
OTA is a more flexible contracting mechanism than CRADA, that can be used for a variety of purposes, including R&D, prototyping, testing, evaluation, and production
OTAs are authorized under the Federal Acquisition Regulation (FAR) and other statutory authorities, which provide broader flexibility in contracting for R&D purposes.
OTAs offer more flexible intellectual property rights arrangements than CRADAs by allowing the parties to negotiate terms throughout the process that best suit their needs
OTAs are exempt from many of the FAR requirements, including competition requirements, allowing the government to work more quickly with non-federal partners.

13🧵OTA's have a financial and liability incentive, instead of directly paying big pharma, and intermediary contract firm makes the agreement, and thus bypasses regulatory oversight and transparency. This gives a lot of wiggle room to negotiate prices, & rights.

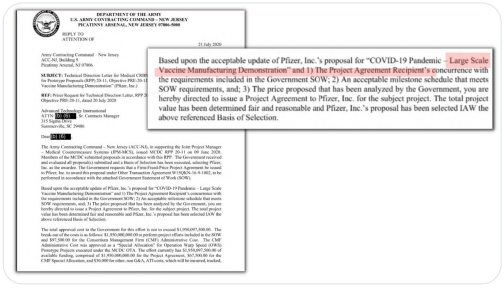

npr
COVID-19 VACCINE CONTRACT ACCOUNTABILITY
How Operation Warp Speed's Big Vaccine Contracts Could Stay Secret
September 29, 2020 · 3:40 PM ET
Heard on All Things Considered
By Sydney Lupkin

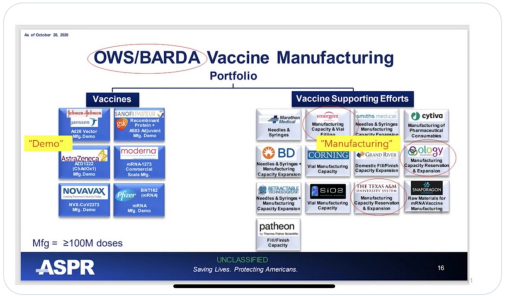

npr
COVID-19 VACCINE CONTRACT ACCOUNTABILITY
How Operation Warp Speed's Big Vaccine Contracts Could Stay Secret
The Trump administration has compared Operation Warp Speed's crash program to develop a COVID-19 vaccine to the Manhattan Project. And like the notoriously secretive government project to make the first atomic bomb, the details of Operation Warp Speed's work may take a long time to unravel.
One reason is that Operation Warp Speed is issuing billions of dollars' worth of coronavirus vaccine contracts to companies through a nongovernment intermediary, bypassing the regulatory oversight and transparency of traditional federal contracting mechanisms, NPR has learned.
Instead of entering into contracts directly with vaccine makers, more than $6 billion in Operation Warp Speed funding has been routed through a defense contract management firm called Advanced Technologies International, Inc.
ATI then awarded contracts to companies working on COVID-19 vaccines.

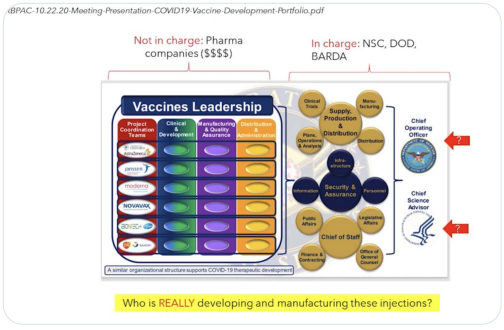
npr
COVID-19 VACCINE CONTRACT ACCOUNTABILITY
How Operation Warp Speed's Big Vaccine Contracts Could Stay Secret
As a result, the contracts between the pharmaceutical companies and ATI may not be available through public records requests, and additional documents are exempt from public disclosure for five years.
Vaccine contracts awarded this way include $1.6 billion for Novavax, $1.95 billion for Pfizer, $1.79 billion for Sanofi and $1 billion for Johnson & Johnson.
Many were OTAs that weakened or excluded Bayh-Dole clauses, which, among other things, allow the government to "march in" and take control of a drug or vaccine if a manufacturer that received federal funding engages in price gouging, for example.

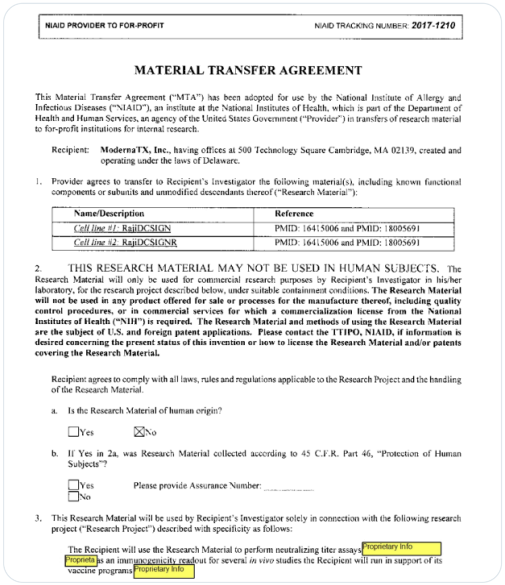

"Large scale vaccine manufacturing demonstration"
Statement of Work
For
COVID-19 PANDEMIC–LARGE SCALE VACCINE MANUFACTURING DEMONSTRATION
RPP #: 20-11
Project Identifier: 2011-003
Consortium Member: Member
Title of Proposal: COVID-19 Pandemic--Large Scale Vaccine Manufacturing Demonstration
Requiring Activity: Joint mission between the Department of Health and Human Services and Department of Defense to combat COVID-19
1.0 INTRODUCTION, SCOPE, AND OBJECTIVES
1.1 Introduction
This Statement of Work (the "Statement of Work") is hereby entered into, effective as of July 21, 2020, pursuant to that certain Project Agreement by and between MCDC and Pfizer dated as of July 21, 2020 ("this Agreement" or "Project Agreement").
Pfizer OTA vaccine contract through MCDC

14🧵We, the unwitting public, were made to believe that the pharmaceutical companies were in charge of the MCMs completely. This was a lie. The Moderna &Pfizer, Sanofi etc contracts for C19 MCMs were never in charge. The intermediaries & USG was.

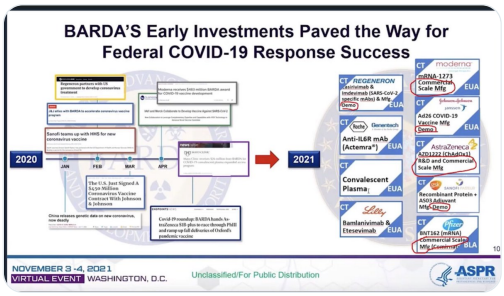

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000
Based upon the acceptable update of Pfizer, Inc.'s proposal for "COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and, 3) The price proposed that has been analyzed by the Government, you are hereby directed to issue a Project Agreement to Pfizer, Inc. for the subject project. The total project value has been determined fair and reasonable and Pfizer, Inc.'s proposal has been selected IAW the above referenced Basis of Selection.

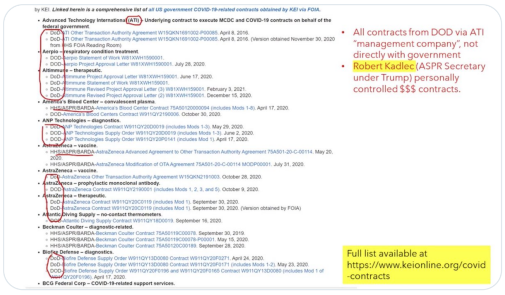


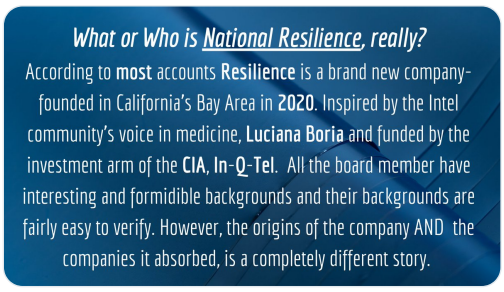

BPAC-10.22.20-Meeting-Presentation-COVID19-Vaccine-Development-Portfolio.pdf
Not in charge: Pharma companies ($$$$)
In charge: NSC, DOD, BARDA
Vaccines Leadership
Chief Operating Officer
Chief Science Advisor
Who is REALLY developing and manufacturing these injections?


NIAID PROVIDER TO FOR-PROFIT
NIAID TRACKING NUMBER: 2017-1210
MATERIAL TRANSFER AGREEMENT
This Material Transfer Agreement ("MTA") has been adopted for use by the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute at the National Institutes of Health, which is part of the Department of Health and Human Services, an agency of the United States Government ("Provider") in transfers of research material to for-profit institutions for internal research.
Recipient: ModernaTX, Inc., having offices at 500 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware.
1. Provider agrees to transfer to Recipient's investigator the following material(s), including known functional components or subunits and unmodified descendants thereof ("Research Material"):
Name/Description
Reference
Cell line #1: RajiDCSIGN
PMID: 16415006 and PMID: 18005691
Cell line #2: RajiDCSIGNR
PMID: 16415006 and PMID: 18005691
2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for commercial research purposes by Recipient's Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. The Research Material will not be used in any product offered for sale or processes for the manufacture thereof, including quality control procedures, or in commercial services for which a commercialization license from the National Institutes of Health ("NIH") is required. The Research Material and methods of using the Research Material are the subject of U.S. and foreign patent applications. Please contact the TTIPO, NIAID, if information is desired concerning the present status of this invention or how to license the Research Material and/or patents covering the Research Material.
Recipient agrees to comply with all laws, rules and regulations applicable to the Research Project and the handling of the Research Material.
a. Is the Research Material of human origin?
Yes
No
b. If Yes in 2a, was Research Material collected according to 45 C.F.R. Part 46, "Protection of Human Subjects"?
Yes
No
Please provide Assurance Number:
3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:
The Recipient will use the Research Material to perform neutralizing titer assays
as an immunogenicity readout for several in vivo studies the Recipient will run in support of its vaccine programs

15🧵Light Bulb Moment for me because now the instance of Moderna using the intelligence community led 'Resilience' to make their C19 💉 makes sense. This OTA empire is a scam to avoid oversight/liability and paint their pockets everything else is "collateral damage"

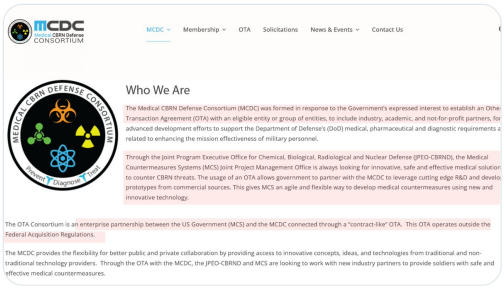


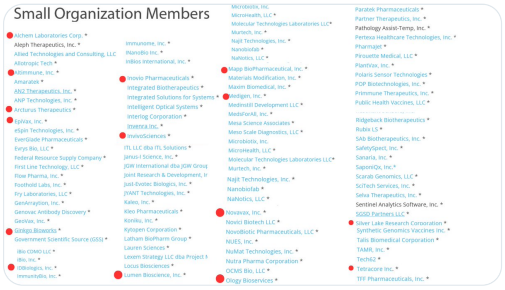

All contracts from DOD via ATI "management company", not directly with government
Robert Kadlec (ASPR Secretary under Trump) personally controlled $$$ contracts.
Full list available at https://www.keionline.org/covid-contracts

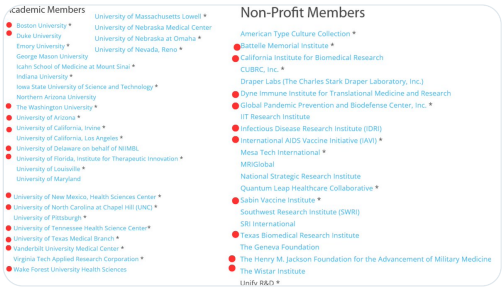

What or Who is National Resilience, really?
According to most accounts Resilience is a brand new company-founded in California's Bay Area in 2020. Inspired by the Intel community's voice in medicine, Luciana Boria and funded by the investment arm of the CIA, In-Q-Tel. All the board member have interesting and formidable backgrounds and their backgrounds are fairly easy to verify. However, the origins of the company AND the companies it absorbed, is a completely different story.

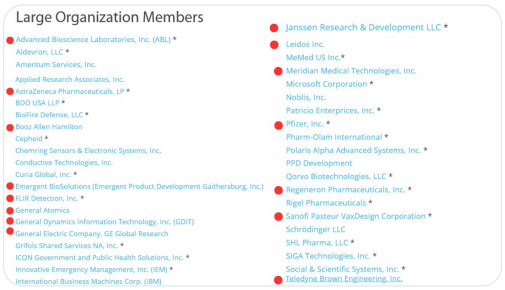
RESILIENCE
U.S. FOOD & DRUG ADMINISTRATION
BILL & MELINDA GATES foundation
iqt IN-Q-TEL
Massachusetts Institute of Technology
ARCH VENTURE PARTNERS
8VC
CONFLICTS OF INTEREST
Borio inspired Nelsen to create Resilience,
-Both sit on the board of ARCH.
-Chris Darby & Borio both lead In-Q-Tel
-Scott Gottlieb was in the FDA. So was: Borio & Mark Mcclellen
-Gottlieb also is in NEA
Oetting & Lonsdale are both in 8VC
David Schenkein is in GV
Over1/2 of those pictured attended the SALT conferences
Backed by investors with an unmatched record of success
8VC
GV
NEA

16🧵The FDA liason for this OTA/FDA arangement is the same person who led to the creation of Resilience. Conflict of interest #860,995,667,382. Almost all of the MCM OTAs use the intermediary called MCDC

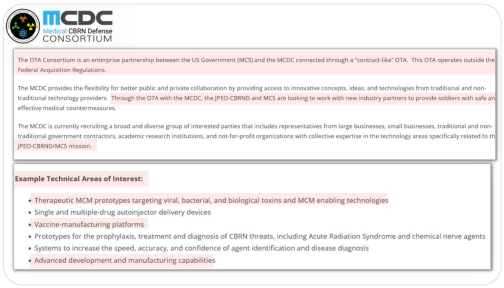

MCDC
CONSORTIUM
MCDC
Membership
OTA
Solicitations
News & Events
Contact Us
Who We Are
The Medical CBRN Defense Consortium (MCDC) was formed in response to the Government's expressed interest to establish an Othe
Transaction Agreement (OTA) with an eligible entity or group of entities, to include industry, academic, and not-for-profit partners, for
advanced development efforts to support the Department of Defense's (DoD) medical, pharmaceutical and diagnostic requirements
related to enhancing the mission effectiveness of military personnel.
Through the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), the Medical
Countermeasures Systems (MCS) Joint Project Management Office is always looking for innovative, safe and effective medical solution
to counter CBRN threats. The usage of an OTA allows government to partner with the MCDC to leverage cutting edge R&D and develo
prototypes from commercial sources. This gives MCS an agile and flexible way to develop medical countermeasures using new and
innovative technology.
The OTA Consortium is an enterprise partnership between the US Government (MCS) and the MCDC connected through a "contract-like" OTA. This OTA operates outside the
Federal Acquisition Regulations.
The MCDC provides the flexibility for better public and private collaboration by providing access to innovative concepts, ideas, and technologies from traditional and non-
traditional technology providers. Through the OTA with the MCDC, the JPEO-CBRND and MCS are looking to work with new industry partners to provide soldiers with safe and
effective medical countermeasures.

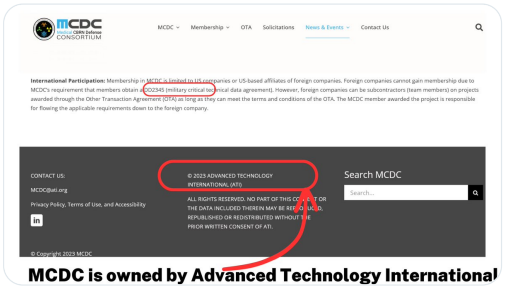


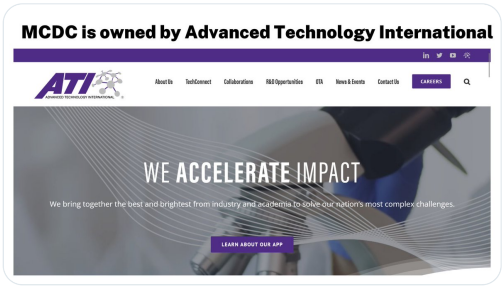

Academic Members
Boston University *
Duke University
Emory University *
George Mason University
Icahn School of Medicine at Mount Sinai *
Indiana University *
Iowa State University of Science and Technology *
Northern Arizona University
The Washington University *
University of Arizona *
University of California, Irvine *
University of California, Los Angeles *
University of Delaware on behalf of NIMBL
University of Florida, Institute for Therapeutic Innovation *
University of Louisville *
University of Maryland
University of Massachusetts Lowell *
University of Nebraska Medical Center
University of Nebraska at Omaha *
University of Nevada, Reno *
University of New Mexico, Health Sciences Center *
University of North Carolina at Chapel Hill (UNC) *
University of Pittsburgh *
University of Tennessee Health Science Center*
University of Texas Medical Branch *
Vanderbilt University Medical Center *
Virginia Tech Applied Research Corporation *
Wake Forest University Health Sciences
Non-Profit Members
American Type Culture Collection *
Battelle Memorial Institute *
California Institute for Biomedical Research
CUBRC, Inc. *
Draper Labs (The Charles Stark Draper Laboratory, Inc.)
Dyne Immune Institute for Translational Medicine and Research
Global Pandemic Prevention and Biodefense Center, Inc. *
IIT Research Institute
Infectious Disease Research Institute (IDRI)
International AIDS Vaccine Initiative (IAVI) *
Mesa Tech International *
MRIGlobal
National Strategic Research Institute
Quantum Leap Healthcare Collaborative *
Sabin Vaccine Institute *
Southwest Research Institute (SWRI)
SRI International
Texas Biomedical Research Institute
The Geneva Foundation
The Henry M. Jackson Foundation for the Advancement of Military Medicine
The Wistar Institute
Unify R&D *


Large Organization Members
Advanced Bioscience Laboratories, Inc. (ABL) *
Aldevron, LLC *
Amentum Services, Inc.
Applied Research Associates, Inc.
AstraZeneca Pharmaceuticals, LP *
BDO USA LLP *
BioFire Defense, LLC *
Booz Allen Hamilton
Cepheid *
Chemring Sensors & Electronic Systems, Inc.
Conductive Technologies, Inc.
Curia Global, Inc. *
Emergent BioSolutions (Emergent Product Development Gaithersburg, Inc.)
FUR Detection, Inc. *
General Atomics
General Dynamics Information Technology, Inc. (GDIT)
General Electric Company, GE Global Research
Grifols Shared Services NA, Inc. *
ICON Government and Public Health Solutions, Inc. *
Innovative Emergency Management, Inc. (IEM) *
International Business Machines Corp. (IBM)
Janssen Research & Development LLC *
Leidos Inc.
MeMed US Inc.*
Meridian Medical Technologies, Inc.
Microsoft Corporation *
Noblis, Inc.
Patricio Enterprises, Inc. *
Pfizer, Inc. *
Pharm-Olam International *
Polaris Alpha Advanced Systems, Inc. *
PPD Development
Qorvo Biotechnologies, LLC *
Regeneron Pharmaceuticals, Inc. *
Rigel Pharmaceuticals *
Sanofi Pasteur VaxDesign Corporation *
Schrödinger LLC
SHL Pharma, LLC *
SIGA Technologies, Inc. *
Social & Scientific Systems, Inc. *
Teledyne Brown Engineering, Inc.

17🧵As you saw they work w/nearly everyone. MCDC (Medical CBRN Defense Consortium) is sponsored by the Government's JPEO-CBRND and managed by a defense contractor.


MCDC
Medical CBRN Defense CONSORTIUM
The OTA Consortium is an enterprise partnership between the US Government (MCS) and the MCDC connected through a "contract-like" OTA. This OTA operates outside the Federal Acquisition Regulations.
The MCDC provides the flexibility for better public and private collaboration by providing access to innovative concepts, ideas, and technologies from traditional and non-traditional technology providers. Through the OTA with the MCDC, the JPEO-CBRND and MCS are looking to work with new industry partners to provide soldiers with safe an effective medical countermeasures.
The MCDC is currently recruiting a broad and diverse group of interested parties that includes representatives from large businesses, small businesses, traditional and non-traditional government contractors, academic research institutions, and not-for-profit organizations with collective expertise in the technology areas specifically related to th JPEO-CBRND/MCS mission.
Example Technical Areas of Interest:
Therapeutic MCM prototypes targeting viral, bacterial, and biological toxins and MCM enabling technologies
Single and multiple-drug autoinjector delivery devices
Vaccine-manufacturing platforms
Prototypes for the prophylaxis, treatment and diagnosis of CBRN threats, including Acute Radiation Syndrome and chemical nerve agents
Systems to increase the speed, accuracy, and confidence of agent identification and disease diagnosis
Advanced development and manufacturing capabilities

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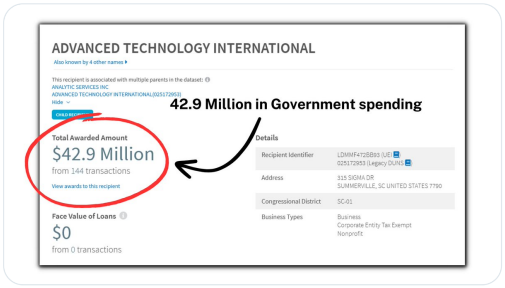
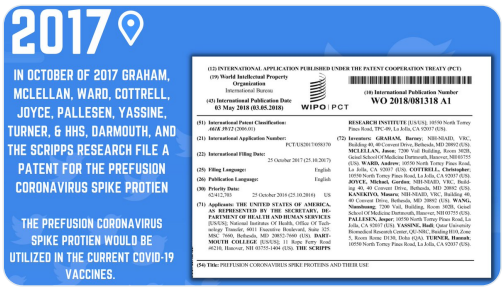


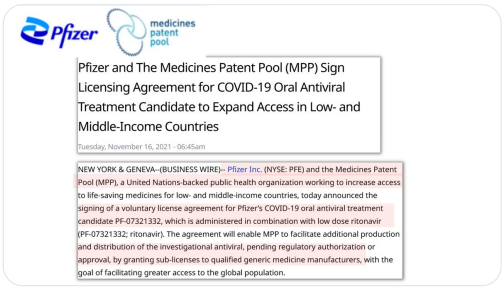
18🧵Now when it comes to intellectual property rights you should know that the OTA is why the NIAID received 400 Million $ from Moderna. Despite their MTA was in 2017 the tech was used directly to make ALL the mRNA 💉

THE VRC/NIAID SIGNS A CONFIDENTIAL AGREEMENT WITH MODERNA FOR THE TECHNOLOGY ON THE MRNA PLATFORM, TO BUILD MCMS NAMELY MONOCLONAL ANTIBODIES.
2015
Confidential Disclosure Agreement

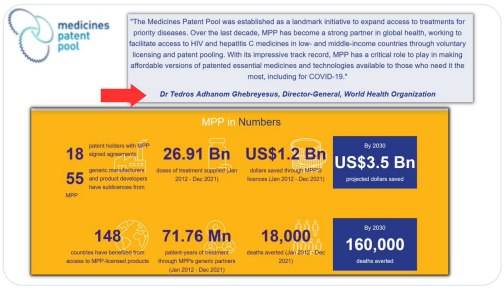
2017
ANDREWS & THE VRC SCIENTISTS GRAHAM, MCLELLAN, AND KIZZMEKIA CORBETT HAD CONTINUED THEIR WORK ON THE PREFUSION MUTATIONS IN CORONAVIRUSES.
FAUCI
GRAHAM
CORBETT
COLLINS
GATES
MASCOLA
Soon after COVID-19 emerged, the new coronavirus, which is closely related to SARS, was recognized as its cause. NIH-funded researchers including Jason McLellan, an alumnus of the VRC and now at The University of Texas at Austin, were ready. They'd been studying coronaviruses in collaboration with NIAID investigators for years, with special attention to the spike proteins.

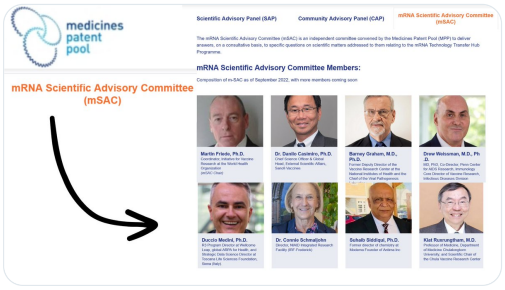

2017
IN OCTOBER OF 2017 GRAHAM, MCLELLAN, WARD, COTTRELL, JOYCE, PALLESEN, YASSINE, TURNER, & HHS, DARMOUTH, AND THE SCRIPPS RESEARCH FILE A PATENT FOR THE PREFUSION CORONAVIRUS SPIKE PROTIEN
THE PREFUSION CORONAVIRUS SPIKE PROTIEN WOULD BE UTILIZED IN THE CURRENT COVID-19 VACCINES.
(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)
WIPO | PCT
(10) International Publication Number
WO 2018/081318 A1
(43) International Publication Date
03 May 2018 (03.05.2018)

19 🧵For distribution equity over patented MCMs the avenues for dispersal went through the Medicines Patent Pool (MPP), est in 2010 by UNITAID, all the C19 jabs are chosen by their mRNA Sci Advisory Committee

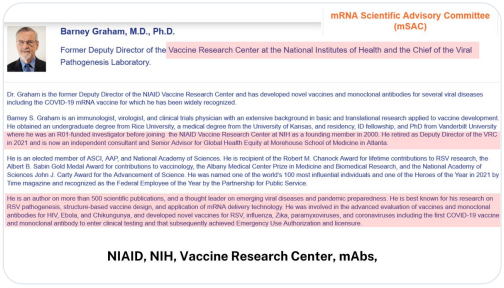

Pfizer
medicines patent pool
Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries
Tuesday, November 16, 2021 - 06:45am
NEW YORK & GENEVA--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and the Medicines Patent Pool (MPP), a United Nations-backed public health organization working to increase access to life-saving medicines for low- and middle-income countries, today announced the signing of a voluntary license agreement for Pfizer's COVID-19 oral antiviral treatment candidate PF-07321332, which is administered in combination with low dose ritonavir (PF-07321332; ritonavir). The agreement will enable MPP to facilitate additional production and distribution of the investigational antiviral, pending regulatory authorization or approval, by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population.

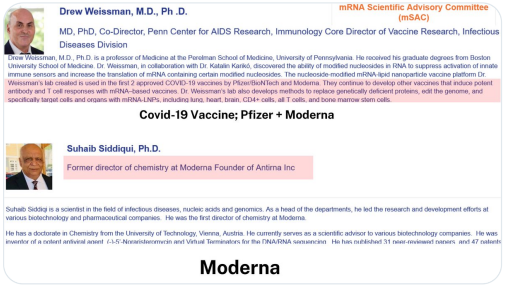
Pfizer
medicines patent pool
About MPP
The Medicines Patent Pool (MPP) is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with eleven patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a long-acting technology and two experimental oral antiviral treatments for COVID-19. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government and SDC. More information at https://medicinespatentpool.org/ and follow us on Twitter, LinkedIn and YouTube.


medicines patent pool
"The Medicines Patent Pool was established as a landmark initiative to expand access to treatments for priority diseases. Over the last decade, MPP has become a strong partner in global health, working to facilitate access to HIV and hepatitis C medicines in low- and middle-income countries through voluntary licensing and patent pooling. With its impressive track record, MPP has a critical role to play in making affordable versions of patented essential medicines and technologies available to those who need it the most, including for COVID-19."
Dr Tedros Adhanom Ghebreyesus, Director-General, World Health Organization
MPP in Numbers
18
patent holders with MPP signed agreements
55
generic manufacturers and product developers have sublicences from MPP
26.91 Bn
doses of treatment supplied (Jan 2012 - Dec 2021)
US$1.2 Bn
dollars saved through MPP's licences (Jan 2012 - Dec 2021)
By 2030
US$3.5 Bn
projected dollars saved
148
countries have benefited from access to MPP-licensed products
71.76 Mn
patient years of treatment through MPP's generic partners (Jan 2012 - Dec 2021)
18,000
deaths averted (Jan 2012 - Dec 2021)
By 2030
160,000
deaths averted

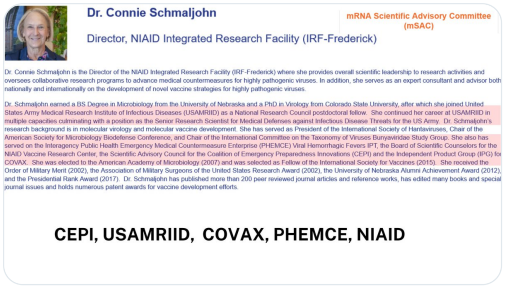


20 🧵And who is on that mRNA tech Transfer for MPP Advisory committee? Founder of Moderna. NIH (the creator of the vax tech from the NIAID). Pfizer. BMGF, CEPI. Covax, USAMRIID (DoD), Sanofi, Merck. No conflicts of interest here...


mRNA Scientific Advisory Committee (mSAC)
Barney Graham, M.D., Ph.D.
Former Deputy Director of the Vaccine Research Center at the National Institutes of Health and the Chief of the Viral Pathogenesis Laboratory.
Dr. Graham is the former Deputy Director of the NIAID Vaccine Research Center and has developed novel vaccines and monoclonal antibodies for several viral diseases including the COVID-19 mRNA vaccine for which he has been widely recognized.
Barney S. Graham is an immunologist, virologist, and clinical trials physician with an extensive background in basic and translational research applied to vaccine development. He obtained an undergraduate degree from Rice University, a medical degree from the University of Kansas, and residency, ID fellowship, and PhD from Vanderbilt University where he was an R01-funded investigator before joining the NIAID Vaccine Research Center at NIH as a founding member in 2000. He retired as Deputy Director of the VRC in 2021 and is now an independent consultant and Senior Advisor for Global Health Equity at Morehouse School of Medicine in Atlanta.
He is an elected member of ASCI, AAP, and National Academy of Sciences. He is recipient of the Robert M. Chanock Award for lifetime contributions to RSV research, the Albert B. Sabin Gold Medal Award for contributions to vaccinology, the Albany Medical Center Prize in Medicine and Biomedical Research, and the National Academy of Sciences John J. Carty Award for the Advancement of Science. He was named one of the world's 100 most influential individuals and one of the Heroes of the Year in 2021 by Time magazine and recognized as the Federal Employee of the Year by the Partnership for Public Service.
He is an author on more than 500 scientific publications, and a thought leader on emerging viral diseases and pandemic preparedness. He is best known for his research on RSV pathogenesis, structure-based vaccine design, and application of mRNA delivery technology. He was involved in the advanced evaluation of vaccines and monoclonal antibodies for HIV, Ebola, and Chikungunya, and developed novel vaccines for RSV, influenza, Zika, paramyxoviruses, and coronaviruses including the first COVID-19 vaccine and monoclonal antibody to enter clinical testing and that subsequently achieved Emergency Use Authorization and licensure.
NIAID, NIH, Vaccine Research Center, mAbs,


mRNA Scientific Advisory Committee (mSAC)
Drew Weissman, M.D., Ph .D.
MD, PhD, Co-Director, Penn Center for AIDS Research, Immunology Core Director of Vaccine Research, Infectious Diseases Division
Drew Weissman, M.D., Ph.D. is a professor of Medicine at the Perelman School of Medicine, University of Pennsylvania. He received his graduate degrees from Boston University School of Medicine. Dr. Weissman, in collaboration with Dr. Katalin Karikó, discovered the ability of modified nucleosides in RNA to suppress activation of innate immune sensors and increase the translation of mRNA containing certain modified nucleosides. The nucleoside-modified mRNA-lipid nanoparticle vaccine platform Dr. Weissman's lab created is used in the first 2 approved COVID-19 vaccines by Pfizer/BioNTech and Moderna. They continue to develop other vaccines that induce potent antibody and T cell responses with mRNA-based vaccines. Dr. Weissman's lab also develops methods to replace genetically deficient proteins, edit the genome, and specifically target cells and organs with mRNA-LNPs, including lung, heart, brain, CD4+ cells, all T cells, and bone marrow stem cells.
Covid-19 Vaccine; Pfizer + Moderna
Suhaib Siddiqui, Ph.D.
Former director of chemistry at Moderna Founder of Antirna Inc
Suhaib Siddiqi is a scientist in the field of infectious diseases, nucleic acids and genomics. As a head of the departments, he led the research and development efforts at various biotechnology and pharmaceutical companies. He was the first director of chemistry at Moderna.
He has a doctorate in Chemistry from the University of Technology, Vienna, Austria. He currently serves as a scientific advisor to various biotechnology companies. He was inventor of a potent antiviral award 4-A-5'-Aboneisobercmcin and Virtual Terminators for the DNA/RNA sequencing. He has published 51 peer-reviewed papers and 47 patents
Moderna

mRNA Scientific Advisory Committee (mSAC)
Dr. Danilo Casimiro, Ph.D.
Chief Science Officer & Global Head, External Scientific Affairs, Sanofi Vaccines
Danilo is Chief Science Officer and Global Head, External Scientific Affairs for Sanofi Vaccines since October 2021. He is responsible for external-facing functions of the Vaccines R&D unit, including teams for search-and-evaluation of vaccine candidates and vaccine innovations, scientific network development & partnerships, and external financing. He has over 25 years of experience in research and development of vaccines and biologics in both pharmaceutical and non-profit sectors. Prior to joining Sanofi in November 2017, he was the Chief Scientific Officer at Aeras, a non-profit vaccine R&D organization funded by the Bill and Melinda Gates Foundation. During his 19 years at the Merck Research Laboratories, Danilo contributed to the licensure of Merck's human papillomavirus (HPV) vaccines, and the development of novel vaccine candidates an antibodies against multiple viral pathogens and novel immunotherapeutic approaches against cancer and neurodegenerative diseases. He also served on numerous advisor committees to the Bill & Melinda Gates Foundation Global Health Program, International AIDS Vaccine Initiative, NIH Integrated Preclinical/Clinical AIDS Vaccine Developme Program, USAID Malaria Vaccine Development Program, and HIV Vaccine Enterprise. He received his Ph.D. degree in chemistry and post-doctoral training from the Californ Institute of Technology and the Scripps Research Institute-La Jolla, respectively.
Bill and Melinda Gates Foundation, Sanofi, Scripps Research Institute, USAID, Merck,


Dr. Connie Schmaljohn
mRNA Scientific Advisory Committee (mSAC)
Director, NIAID Integrated Research Facility (IRF-Frederick)
Dr. Connie Schmaljohn is the Director of the NIAID Integrated Research Facility (IRF-Frederick) where she provides overall scientific leadership to research activities and oversees collaborative research programs to advance medical countermeasures for highly pathogenic viruses. In addition, she serves as an expert consultant and advisor both nationally and internationally on the development of novel vaccine strategies for highly pathogenic viruses.
Dr. Schmaljohn earned a BS Degree in Microbiology from the University of Nebraska and a PhD in Virology from Colorado State University, after which she joined United States Army Medical Research Institute of Infectious Diseases (USAMRIID) as a National Research Council postdoctoral fellow. She continued her career at USAMRIID in multiple capacities culminating with a position as the Senior Research Scientist for Medical Defenses against Infectious Disease Threats for the US Army. Dr. Schmaljohn's research background is in molecular virology and molecular vaccine development. She has served as President of the International Society of Hantaviruses, Chair of the American Society for Microbiology Biodefense Conference, and Chair of the International Committee on the Taxonomy of Viruses Bunyaviridae Study Group. She also has served on the Interagency Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Viral Hemorrhagic Fevers IPT, the Board of Scientific Counselors for the NIAID Vaccine Research Center, the Scientific Advisory Council for the Coalition of Emergency Preparedness Innovations (CEPI) and the Independent Product Group (IPG) fo COVAX. She was elected to the American Academy of Microbiology (2007) and was selected as Fellow of the International Society for Vaccines (2015). She received the Order of Military Merit (2002), the Association of Military Surgeons of the United States Research Award (2002), the University of Nebraska Alumni Achievement Award (2012), and the Presidential Rank Award (2017). Dr. Schmaljohn has published more than 200 peer reviewed journal articles and reference works, has edited many books and special journal issues and holds numerous patent awards for vaccine development efforts.
CEPI, USAMRIID, COVAX, PHEMCE, NIAID

21 🧵To make a long thread longer- We weren't just conned we were outsmarted, out maneuvered but they won't outlast us. The unethical, 2 faced, illegal entanglement they made will hang them out to dry. P.S- THEY'RE LYING 2 All of US. Don't accept that!❤️

• • •